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37492 7590 05/21/2008 CELERA, AN APPLERA BUSINESS UNIT 1401 HARBOR BAY PARKWAY			EXAMINER	
			KAPUSHOC, STEPHEN THOMAS	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Advisory Action

## Part 5.

Applicants' amendments to the claims of 4/21/2008 has overcome some of the rejections of the claims as presented in the Final Office Action of 8/10/2007 as follows:

The objections to claims 27, 37, 47, and 57 are **WITHDRAWN** in light of the cancellation of those claims.

The objections to claims 29, 39, 49, and 59 are **WITHDRAWN** in light of the amendments to those claims to recite 'the genomic sequence of the PTPN22 gene'

The rejection of claims 1 and 27-45 under 35 USC 112 2<sup>nd</sup> ¶ as indefinite is **WITHDRAWN** in light of the cancellation of claims and the amendment to claim 36 requiring that the presence of T at position 101 of SEQ ID NO: 36673 is indicative of an increased risk of the specific phenotype.

The rejection of claims 1, 29-31, 33-36, 39-46, 49-56, and 59-65 under 35 USC 112 1<sup>st</sup> ¶ for lack of adequate written description for new matter is **WITHDRAWN** in light of the cancellation of claims and the amendments to the claims to require the particular phenotype of risk for developing RF-positive rheumatoid arthritis.

The rejection of claims 1 and 27-45 under 35 USC 112 1<sup>st</sup> ¶ for lack of adequate written description is **WITHDRAWN** in light of the cancellation of claims and the

amendments to the claims to require the detection of particular nucleotide content as indicative of the associated phenotype.

The previous Office Action rejected claims 1 and 27-65 under 35 USC 112 1<sup>st</sup> ¶ for not being enabled for the full scope of the claims. The rejection is **WITHDRAWN** from claims 1, 27-35, 37, 38, 47, 48, 57, and 58 which are cancelled. The rejection is also **WITHDRAWN** form pending claims 36, and 39-45 which require the association of the specific nucleotide content of T at position 101 of SEQ ID NO: 36673 with and increased risk for developing RF-positive rheumatoid arthritis.

The rejection of claims 46, 49-56, and 59-65 is **MAINTAINED**. The rejected claims are drawn to methods requiring association of a C at position 101 of SEQ ID NO: 36673 with a decreased risk for developing RF-positive rheumatoid arthritis. As set forth in the rejection, the specification does not provide any genotype analysis, and as such it is possible only to conclude that the T allele in either the T/T or C/T genotype is indicative of increased risk of RF+-RA, and C/C genotype is indicative of decreased risk of RF+ RA. As the claims thus encompass (for example claim 56) associating a T/C genotype with both an increased risk for developing RF+ RA and a decreased risk for developing RF+ RA, the rejection is maintained.

Claims 36 and 39-45 are indicated as allowable. The claims require detection of a T at position 101 of SEQ ID NO: 36673, and association of the particular nucleotide content with an increased risk for developing RF+ RA. The association is supported by

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the teachings of the specification (i.e. Table 6), and is not taught or suggested by the teachings of the prior art.

## Part 11.

The request for reconsideration of the claims as amended has been considered but does not put the application in condition for allowance. As detailed above, claims 46, 49-56, and 59-65 remain rejected as set forth in the previous Office Action under 35 USC 112 1<sup>st</sup> ¶ for lack of enablement. The enabled scope, as based on the teachings of the specification, requires that the presence of the C/C genotype (where Table 6 indicates that the T allele, which may be in a T/T of T/C genotype, is indicative of an increased risk for RF+ RA) is indicative of a decreased risk for developing RF+ RA. As presented, the claims encompass associating any C-containing genotype with a decreased risk for developing RF+ RA.